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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIXIAO WANG
and JOHN JIANHUA CHEN

Appeal 2009-000077
Application 10/797,996
Technology Center 1700

Decided: September 18, 2009

Before, EDWARD C. KIMLIN, CHUNG K. PAK, and
CHARLES F. WARREN, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

DECISION ON APPEAL

Applicants appeal to the Board from the decision of the Primary Examiner finally rejecting claims 18 and 23 through 26 in the Office Action mailed July 16, 2007. 35 U.S.C. §§ 6 and 134(a) (2002); 37 C.F.R. § 41.31(a) (2007).

We reverse the decision of the Primary Examiner.

Claim 18 illustrates Appellants' invention of a method of forming a balloon comprising at least three layers, and is representative of the claims on appeal:

18. A method of forming a balloon comprising at least three layers comprising the steps of:

- i) providing first, second and third tubes, the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene;
- ii) inserting the first tube into the second tube;
- iii) inserting the second tube into the third tube;
- iv) inserting the first, second and third tubes into a balloon mold;
- v) expanding the first, second and third tubes at a desired temperature so as to form a balloon.

The Examiner relies upon the evidence in these references (Ans. 3):¹

Gore	3,953,566	Apr. 27, 1976
Crocker	5,843,116	Dec. 1, 1998

Appellants request review of the ground of rejection under 35 U.S.C. § 103(a) (App. Br. 3): appealed claims 18 and 23 through 26 over Crocker in view of Gore. Ans. 4.

Issue

The issue in this appeal is whether Appellants have shown that the evidence in the combined teachings of Crocker and Gore does not support the Examiner's finding of prima facie obviousness with respect to the claimed copolymer encompassed by representative independent claims 18 and 23.

¹ We consider the Appeal Brief filed February 26, 2008, the Examiner's Answer mailed May 9, 2008, and the Reply Brief filed June 17, 2008.

Claim Interpretation

The plain language of independent claims 18 and 23 encompasses any method of forming a balloon comprising at least the steps of, among other things, inserting any first tube into a second tube “made of a material selected from the group consisting of fluoropolymers and high density polyethylene” in claim 18 and of “expanded PTFE,” that is, polytetrafluoroethylene, in claim 23; and inserting the second tube with the first tube therein, into the third tube. In claim 18, the thus combined tubes are inserting into a balloon mold, and expanded at any temperature to form a balloon. In claim 23, the thus combined tubes are laminated together to form a three tube laminate. *See, e.g., In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1378-79 (Fed. Cir. 2007); *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004), and cases cited therein; *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997). The transitional term “comprising” opens claims 18 and 23 to encompass any methods which include any manner of additional steps and materials. *See, e.g., In re Baxter*, 656 F.2d 679, 686 (CCPA 1981) (“As long as one of the monomers in the reaction is propylene, any other monomer may be present, because the term ‘comprises’ permits the *inclusion* of other steps, elements, or materials.”).

Claims 18 and 23 do not limit the length of any of the three tubes. Thus, claims 18 and 23 encompass methods of making balloons wherein the first and third tubes are longer than the second tube. Spec., e.g., 4-5 and Figs. 2-6. Claims 18 and 23 also encompass methods wherein the first tube is inserted into the second tube and further into a similar tube, such that the middle layer of the construct is discontinuous. Spec., e.g., 6:8-12 and

Fig. 7c.

We interpret the term “high density polyethylene” in claim 18 to have its common meaning to one of ordinary skill in the art in light of the Specification of unbranched or slightly branched, semicrystalline polymers produced by ethylene polymerization, which have a density of $\geq 0.940 \text{ g/cm}^3$ or higher.² Spec. 4:15. Accordingly, we agree with Appellants that, contrary to the Examiner’s position, the term “high density polyethylene” is not generic to cross-linked polyethylenes. Ans. 8; App. Br. 5-6; Reply Br. 4. We also interpret the term “expanded PTFE” in claim 23 to have its common meaning to one of ordinary skill in the art in light of the Specification. See Spec. 4:20-30.

Findings of Fact

We find Crocker would have disclosed to one of ordinary skill in this art, as illustrated by embodiments depicted in Figure 3, inflation balloon 18 having proximal segment 26, distal segment 28 and central focal segment 30, with nondistensible expansion limiting bands 40, 44 disposed at the proximal and distal ends, respectively, of balloon 18 sandwiched between inner balloon 36 and outer balloon 38. Crocker col. 5, ll. 6-27 and 53-55, and Fig. 2. “[T]he bands 40 and 44 each comprise a tubular section of polyester,” or “[o]r other generally nondistensible materials such as nylon, polyamide, Kevlar fiber, cross-linked polyethylene, polyethylene terephthalate, and others, . . . to accomplish the expansion-limiting effect.”

² See, e.g., Yury V. Kissin, “High Density Polyethylene,” *Olefin Polymers(Polyethylene)*, in 17 Kirk-Othmer Encyclopedia of Chemical Technology, 724-56 (4th ed., John Wiley & Sons, 1996).

Crocker col. 5, ll. 28-52. “Balloon 18 can be provided with two or more layers as illustrated.” Crocker col. 5, ll. 60-61, and Figs. 2 and 3.

We find Crocker discloses that inner and outer balloons 36, 38 can be separately mounted on tubular body 12 of catheter 10, with expansion limiting bands 40, 44 sandwiched therebetween, and the balloon structure inserted into a Teflon capture tube or mold, blown to a certain diameter, and heated to about 300°F, that is about 148.8°C. Crocker col. 6, l. 18 to col. 7, l. 62, and Figs. 2-3. In this respect, Crocker discloses inner balloon 36 is mounted on tubular body 12; expansion limiting bands 40, 44 positioned on proximal and distal segments 26, 28 of inner balloon 36; and “outer balloon 38 is advanced axially over the inner balloon 36 and the expansion limiting bands 40 and 44.” Crocker col. 6, l. 63 to col. 7, l. 25.

We find Gore discloses a process for producing a PTFE polymer which has an amorphous content exceeding about 5% and has high porosity and high strength, and can be used to produce stretched shaped articles, such as tubes, by expanding paste-formed, shaped articles of PTFE polymer; stretching the article in one or more directions, and heating the stretch-shaped article in the range of 35°C to 327°C, followed by cooling. Gore, e.g., abstract, col. 1, ll. 21-57, col. 2, ll. 7-49, and col. 3, ll. 4-37. “When the expanded products are heated to above the lowest crystalline melting point of the poly(tetrafluoro-ethylene), disorder begins to occur in the geometric order of the crystallites and the crystallinity decreases, with concomitant increase in the amorphous content of the polymer, typically to 10% or more,” which can “be considered an amorphous locking process.” Gore col. 3, ll. 49-60. “[H]eat treatment above 327°C. causes a surprising increase in

strength,” and “[t]he optimum heat treating temperature is in the range of 350°C to 370°C and the heating periods required may range from about 5 seconds to about 1 hour.” Gore col. 3, ll. 63 to col. 4, ll. 5. Gore illustrates an expanded tube in Example 8 in which extruded “‘Teflon’ 6A poly(tetrafluoroethylene) tubing” is heated to about 300°C in an oven, then expanded with compressed air, and further heated to about 360°C for five minutes. The highly permeable, “expanded, amorphous-locked tubing” is disclosed to be useful as a filter membrane. Gore col. 14, ll. 16-68; *see also* Gore col. 5, ll. 20-29.

Opinion

We are of the opinion Appellants have shown that the evidence in the combined teachings of Crocker and Gore does not support the Examiner’s finding of prima facie obviousness with respect to the claimed copolymer encompassed by representative independent claims 18 and 23.

We initially disagree with Appellants that Crocker’s process does not form a balloon by following the same steps specified in claims 18 and 23. Reply Br. 2-3. Indeed, as the Examiner points out, one of ordinary skill in this art would have reasonably inferred that Crocker’s process involves the insertion of inner balloon or tube 36 into bands or tubular sections 40, 44, which structure is then inserted into outer balloon or tube 38, with the structure then inserted into a mold, inflated and heated.³ Ans. 4-5 and 7. *See above* pp. 3-4 and 5.

³ It is well settled that a reference stands for all of the specific teachings thereof as well as the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom, *see In re Fritch*, 972 F.2d 1260, 1264-65 (Fed. Cir. 1992); *In re Preda*, 401 F.2d 825, 826-27 (CCPA

Accordingly, Crocker's method differs from the claimed method encompassed by claims 18 and 23 only in the materials used to form the second bands or tubes 40, 44, as the Examiner points out. Ans. 4-5 and 7. In this respect, we agree with Appellants that, contrary to the Examiner's position, the "cross-linked polyethylene" taught by Crocker for nondistensible expansion limiting bands or tubes 40, 44 is not encompassed by the claim term "high density polyethylene" in claim 18.⁴ Ans. 8. App. Br. 4-6; Reply Br. 4. *See above* p. 4.

The Examiner further relies on Gore for "a PTFE . . . tubular product . . . having a porous or dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands." The Examiner submits one of ordinary skill in this art would have used Gore's PTFE product in Crocker's method because Crocker's process prepares a laminate and Gore suggests that the PTFE product can be used in laminated structures, and the high strength of Gore's product would provide Crocker with the limited expansion of the balloon. Ans. 4-5 and 9, citing Gore col. 14, ll. 17-20, and col. 1, ll. 30 and 39-40, and Crocker col. 5, ll. 28-30 and 46-52, and col. 7, ll. 8-62. *See above* pp. 4

1968), presuming skill on the part of this person. *In re Sovish*, 769 F.2d 738, 742-43 (Fed. Cir. 1985).

⁴ We have not considered the Examiner's argument that Appellants acknowledge that high density polyethylene is known to be useful in catheter balloons because of a teaching in a United States Patent incorporated by reference in the Specification. Indeed, this reference is not applied in the ground of rejection advanced on appeal. Ans. 8. *See In re Hoch*, 428 F.2d 1341, 1342 n. 3, (CCPA 1970); *cf. Ex parte Raske*, 28 USPQ2d 1304, 1304-05 (BPAI 1993).

and 6. Thus, the Examiner argues the substitution of Gore's material for that of Crocker would obtain predictable results and thus would have been obvious. Ans. 9-10.

Appellants submit that there is no teaching in Crocker leading one of ordinary skill in this art to use Gore's PTFE product in place of the polymeric material taught by Crocker to be useful for nondistensible expansion limiting bands or tubes 40, 44. App. Br. 5 and 6-8. Appellants point out that Gore's product is porous, and is not similar to the polymers used by Crocker. App. Br. 7; Reply Br. 4-5.

On this record, we agree with Appellants that the Examiner has not established that Gore's expanded, amorphous-locked tubing PTFE product illustrated in Gore Example 8, which has been formed of PTFE and shaped into the desired product which is then stretched and heated to form a porous structure of high strength, is so similar to the polymers disclosed by Crocker for nondistensible expansion limiting bands or tubes 40, 44 that one of ordinary skill in this art would have been led to use Gore's expanded, amorphous-locked tubing PTFE product to form bands or tubes 40, 44 in Crocker's process. *See above* pp. 4-6. *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007) ("[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."); *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006); *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) ("hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at

appellant's claimed invention has not been explained); *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."); *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967).

Accordingly, the Examiner has not established a prima facie case of obviousness with respect to appealed independent claims 18 and 23. Therefore, we reverse the ground of rejection of the appealed claims advanced on appeal under 35 U.S.C. § 103(a).

Even if the Examiner did establish that Gore's PTFE product would have been considered by one of ordinary skill in this art to be useful in Crocker's method, the Examiner has not established that Gore's PTFE product satisfies the "expanded PTFE" limitation in claim 23.

The Primary Examiner's decision is reversed.

REVERSED

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